APPENDIX 2

BIBLIOGRAPHY / PUBLISHED ARTICLES / ABSTRACTS

A. Dislocation Rate

1. Ali Khan, M.A., Brakenbury, P.H., Reynolds, I.S.: Dislocation Following Total Hip Replacement. *Journal of Bone and Joint Surgery (Br)*, 198 1; 63-B(2): 2 14-8

2. Hedlundh, U., et al: Surgical Experience Related to Dislocations after Total Hip Arthroplasty. *Journal of Bone and Joint Surgery (Br)*, 1996 March; 78(2): 206-9

3. Kristiansen, B., Jorgensen, L., Holmich, P.: Dislocation Following Total Hip Arthroplasty. *Arch Orthop Trauma Surg*, 1985; 103(6):375-7

4. Madley, S.M., et al: Charnley Total Hip Arthroplasty with Use of Improved Techniques of Cementing. The Results after a Minimum of Fifteen Years of Follow-up. *Journal of Bone and Joint Surgery*, 1997 January; 79(1): 53-64

5 Morrey, B.F.: Difficult Complications after Hip Joint Replacement. Dislocation. *Clinical Orthopedics*, 1997 November; (344): 179-87

6. Paterno, S.A., et al: The Influence of Patient Related Factors and the Position of the Acetabular Component on the Rate of Dislocation after Total Hip Replacement. *Journal of Bone and Joint Surgery*, 1997 August; 79(8):1202- 10

7. Schulte, K.R., et al: The Outcome of Charnley Total Hip Arthroplasty with Cement After a Minimum of Twenty Year Follow-up. The Results of One Surgeon. *Journal of Bone and Joint Surgery*, 1993 July; 75(7): 961-75

8. Turner, R. S. : Postoperative Total Hip Prosthetic Femoral Head Dislocations. Incidence, Etiologic Factors, and Management. *Clinical Orthopedics*, 1994 April, (30 1): 196-204

9. Woo, R.Y., Morrey, B.F.: Dislocations after Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*, 1982 December; 64(9): 1295-306

B. Constrained Hip Replacement

10 Anderson, M.J., Murray, W.R., Skinner, H.B.: Constrained Acetabular Components. *Journal of Arthroplasty*, 1994 February, 9(1): 17-23

11 Cameron, H.U. : Use of a Constrained Acetabular Component in Revision Hip Surgery. *Contemporary Orthopaedics* 1991 November, 23(5): 481-4

12. Fisher, D. A., Kiley, K.: Constrained Acetabular Cup Disassembly. *Journal of Arthroplasty*, 1994 June; 9(3): 325-9

13. Goetz, D. D., Capello, W.N., et al: Salvage of a Recurrently Dislocating Total Hip Prosthesis with Use of a Constrained Acetabular Component. A Retrospective Analysis of Fifty-six Cases. *Journal of Bone and Joint Surgery*, 1998 April; 80(4): 502-9

14. Goetz, D. D., et al: Salvage of Total Hip Instability with a Constrained Acetabular Component, *Clinical Orthopaedics*, 1998 October, (355): 17 l-8 1.

15. Kaper, B. P., Bernini, P.M. : Failure of a Constrained Acetabular Prosthesis of a Total Hip Arthroplasty. *Journal of Bone and Joint Surgery*, 1998 April 80(4): 56 1-5

16. Lombardi, A.V., Jr., Mallory, T.H., Kraus, T. J., Vaughn, B.K., Preliminary Report on The S-ROM Constraining Acetabular Insert: A Retrospective Clinical Experience. *Orthopedics*, 1991 March, 14(3): 297-303

TABLE II-A (Also See Appendix 2)

Dislocation Rate Following Total Hip Replacement

Reference Dislocation Rate	No. of Cases
Ali Khan MA, et al (1) 2.1%	6774
Hedlundh U, et al (2) 3.0%	4230
Kristiansen B, et al (3) 4.9%	427
Madley SM, et al (4) 2.0%	357
Morrey BF (5) 2-3%	35,000
Paterno SA, et al (6) 6.0%	560
Schulte KR, et al (7) 1.0%	322
Turner RS (8) 4.5%	561
Woo RY, Morrev BF (913.2%	10,500
Totals 3.3% Average (1-6% Range)	58,731

LITERATURE REVIEW TABLE

	Anderson, et al (10) Journal Arthop	
	J & J S-ROM May 1987 – Oct. 1990 2 1 Consecutive Cases (one tumor patient excluded)	
Follow-Up	Ave. 31 months Range 24-64 months	
Demographic Data		
Average Age	65.5 years Range 37.5 – 88.5 years	
Average Weight		
Sex	10 male – 11 female	
Indications	Revision Total Hip (8 had liner change only) 3 Intraopera'ive Instability 18 Chronically Dislocating	
Primary Diagnosis	Osteoarthrosis Post-Traumatic Arthritis Avascular Necrosis Congenital Dislocation Rheumatoid Arthritis Postsepsis	10 patients 4 patients 3 patients 2 patients 1 patient 1 patient
Safety Data		
Infection (Deep and Superficial)	Deep sepsis Peroneal nerve palsy	1 patient 2 patients
Implant Malposition		
Implant Failure		
Dislocation		
Recurrent Dislocation	6 patients (29%) dislocated - time from implantation to dislocation averaged 10 months	
Effectiveness		
HHS Excellent 90-100 points	7 patients	
HHS Good 80-90 points	2 patients	
HHS Fair 70-80 points	2 patients	
HHS Poor < 70 points	10 patients	
Recurrent dislocation or progressive loosening suggestive of impending failure	15 patients (71%) experienced no subsequent dislocation	

Discussion –

Of the 10 outcomes considered poor, 6 were due to dislocations, and 4 were due to low HHS scores due to analgesic use. Of the 4, 2 suffered from severe chronic lower back pain due to multiple back surgeries (no hip pain), and 2 had multiple revisions. All were pleased with the constrained device due to freedom from recurrent dislocations.

Comments

No acetabular migration was seen in any patient. Of the two patients with cemented cups, one died of unrelated caused, and one suffered recurrent dislocation 6 months after implantation with no evidence of loosening, radiographically or clinically. Of the remaining 19 patients with porous ingrowth acetabular components, only 3 developed any evidence of lucent lines (with no progression).

LITERATURE REVIEW TABLE

	Cameron, Hugh U. (11) Contemporary Orthop
	J & J S-ROM 1991 6 Revision Cases Performed Over 4 years 1 Case Report Described
Follow-Up	2 years
Demographic Data	
Average Age	58 years
Average Weight	
Sex	1 male
Indications	Patient had 12 previous hip surgeries and a semi-constrained hip was used for revision of 7 year old G . Jlestone (allografts used) followed by recurrent dislocation
Primary Diagnosis	Recurrent Dislocation – following multiple hip surgeries
Discussion	Postoperative dislocation followed by closed reduction, and then redislocation. Allografts were allowed to heal 6 mos. and hip was revised with constrained socket.

Safety Data and Effectiveness

At two years follow-up, the hip remained stable and pain free. Patient wore a hip abduction brace for 6 mos. post op.

LITERATURE REVIEW TABLE

	Fisher, D.A. and Kiley, K. (12) Journal Arthrop J & J S-ROM 1994 2 Case Reports Described
Follow-Up	Case 1 10 years approx.(revision of THR with a constrained hip followed by revision with a second constrained hip) Case 2 8 years approx.(THR for severe degenerative arthritis, 5 dislocations and infected 4 mos. post op, cup revised to constrained, 5 mos. later cup again revised due to trauma)
Demographic Data	
Age	Case 1 66 years Case 2 79 years
Average Weight	
Sex	2 females
Indications	Case 1 Revision of previous THR involving femoral fracture using constrained hip, subsequent dislocation and revision with 2nd constrained hip Case 2 Recurrent dislocation, loose metal shell, trauma (fell down stairs) causing need for 2nd cup revision with constrained hip
Primary Diagnosis	Case 1 Recurrent Dislocation following multiple hip surgeries Case 2 Recurrent dislocation following THR, and trauma
Discussion	Case 1 Revision THR using a constrained cup with joint instability due to fracture of femur, dislocation required 2nd revision with constrained cup Case 2 Falling down stairs caused constrained liner to disassociate from metal shell. She had previous sepsis and cultures had no growth at revision,

Safety Data and Effectiveness	Case 1 18 month follow-up from latest revision with sequential radiographs showing no evidence of wear or deformity of polyethylene. No further problems with the hip. Ambulates with a walker. Case 2 18 months following her second revision, she continues to have a useful hip and is ambulatory with a cane. Radiographically, she has no evidence of interface demarcation, polyethylene failure, or separation.
Discussion	
The author reports that the constrained liner has been used in other patients with few adverse consequences. In the senior author's private practice, 51 patients have received a constrained liner for either recurrent dislocations or extensive revisions with sufficient intraoperative instability to require additional constraint. Five of the 51 patients (10%), including these two cases, have suffered an additional dislocation (3 patients) or disassociation (2 patients). All five of these cases required open reduction or revision of the component.	

LITERATURE REVIEW TABLE

	Goetz D.D., et al (13) JBJS
	Osteonics Omnifit April 1988 – Feb. 1993 55 Patients (56 components -1 female bilateral) (one patient lost to follow-up)
Follow-Up	Ave. 64 months Range 37-97 months
Demographic Data	
Average Age	71 years Range 3 1 – 92 years
Operative Hip	31 Right 25 Left
Sex	19 male – 36 female
Indications	Recurrent Dislocation 56 hips had an average of 6 dislocations each Range 2 – 20 dislocations
Primary Diagnosis	Osteoarthrosis 34 patients Post-Traumatic Arthrosis 10 patients Osteonecrosis 3 patients Congenital Dislocation 2 patients Rheumatoid Arthritis 8 patient Postsepsis 1 patient

Discussion

An average of 3 previous procedures (range l-12 procedures) had been performed on these 56 hips. 7 hips (all with a history of infection) had had a Girdlestone arthroplasty, 6 had a bulk femoral or acetabular allograft, 3 a protrusio cage, 2 an arthrodesis, 2 a periprosthetic fracture, and 1 a proximal femoral replacement prosthesis. In addition, 2 patients were mentally retarded, and another 8 had severe confusion or Alzheimer disease.

Safetv Data and Effectiveness

At latest follow-up: 38 patients (39 hips) were alive, 16 had died, 1 was lost. 55 hips (98%) were followed. Living patients had 64 mos. average follow-up (range 37-97 mos.), and deceased patients had 27 mos. average follow-up (range 1-81 mos.).

38 living patients (39 hips)

Pain	Functior	Walking Aids*
28 (72%) No Pain	19 No Limp	12 No Support
7 (18%) Mild Pain	12 Mild Limp	14 Cane
3 (8%) Moderate Pain	6 Moderate Limp	11 Crutches/Walker
1 (3%) Severe Pain	2 Unable to Walk	2 Wheelchair

***wheelchair, walker, & crutches patients had factors not related to the hip contributing to their disability**

16 hips in patients who had died

2 patients needed reoperation for in. ection debridement
1 patient was revised for recurrent dislocation

Complications

38 Living Patients (39 Hips)	16 Hips in Patients Who Died
1 (3%) Recurrent Dislocation	1 Recurrent Dislocation
5 (13%) Reoperation	2 Infection
2 infection	
1 allograft failure	
1 periprosthetic fracture	
1 aseptic cup loosening	

In addition to complications requiring reoperation, these complications not related to the device occurred: 10 patients had trochanteric nonunion, 1 deep venous thrombosis, 2 intraoperative fractures, 1 incomplete sciatic nerve palsy, and 1 severe heterotopic ossification.

Discussion

The constrained acetabular component successfully prevented instability in 38 (97%) of 39 hips in the living patients after an average duration of follow-up of 5 years. It is important to realize that the primary goal was a stable hip with no additional dislocations. The clinical results in terms of pain, limp and walking ability were difficult to interpret due to the patient population. 27 (49%) of the 55 patients were more than 75 years old, 20 (36%) had severe mental impairment, and several had severe physical disability unrelated to the hip. Due to the limited indications for this device, a homogenous population of patients is not available.

	Goetz, D.D. et al (14) Clinical Orthop.
	Osteonics Omnifit Apr. 1988 – Feb. 1993 98 Patients (101 Hips) (one patient lost to follow-up)
Follow-Up	Average 61 months for 74 living patients (77hips) Range 24-97 months Average 19 months for 23 deceased patients (23 hips) Range 1-8 1 months One patient lost to follow-up at 8 months
Average Age	71 Years Range 3 l-92 years
Operative Hip	54 Right 47 Left
Sex	36 Males 65 Females
Indications	56 Cases for Recurrent Dislocation (average of 6 dislocations, range 2-20 months) 38 Cases for Intraoperative Instability 7 Cases for Neurologic Impairment
Primary Diagnosis	5 1 Hips – Osteoarthritis 28 Hips – Post Traumatic Osteoarthritis 9 Hips – Inflammatory Arthritis 6 Hips – Congenital Hip Dysplasia 4 Hips – Infection 2 Hips – Osteonecrosis 1 Hip – Inflammatory Arthritis & Osteonecrosis
Complications	Cumulative to the time of latest follow-up <u>Deceased Patients</u> 2 of 23 (9%) had Recurrent Dislocation 2 of 23 (9%) had Reoperation for debridement of infection with no removal of components <u>Living Patients</u> 2 of 77 (3%) had Recurrent Dislocation 10 of 77 (13%) had reoperation for reasons other than dislocation or instability (5 infection, 2 allograft failure, 1 internal fixation of fracture, 1 debridement of heterotopic bone)

Other Complications Reported	Trochanteric Nonunion	16 Cases
	Venous Thrombosis	2 Cases
	Intraoperative Fracture	5 Cases
	Incomplete Nerve Palsy	3 Cases
	Intraoperative Hemorrhage	2 Cases
	Decubitis Ulcer	1 Case
	Severe Heterotopic Ossific.	1 Case
	Prostate Resection	1 Case
	Postop Cardiac Death	1 Case
	Postop Lower Gastrointestinal Complications/ Death	1 Case

Results At latest follow-up

Pain

68 patients – No pain
16 patients – Mild
8 patients – Moderate
4 patients – Severe
Remainder Unknown
96 patients with known pain status

Limp

35 patients – No limp
3 5 patients – Mild
16 patients – Moderate
6 patients – Severe
5 patients – Unable to ambulate
97 patients with known gait status

Walking Aids

23 patients – No support required
29 patients – Cane
35 patients – Crutches / walker
10 patients – Wheelchair confined
97 patients with known ambulatory status

Discussion

At latest follow-up, 90 (92%) of the 98 patients (or family members) reported that the operation had improved their quality of life. Only 6 of the 16 patients who required reoperation during the follow-up period thought the placement of the constrained implant had not improved their quality of life. In all cases, patients who had used crutches, a walker, or a wheelchair had factors unrelated to the hip that contributed to their disability. 48 (49%) of the 98 patients were more than 75 years old, and 3 1 (32%) had mental impairment from mental retardation , or dementia.

LITERATURE REVIEW TABLE

	Kaper, B.P., et al (15) JBJS
	J & J S-ROM 1989/1996 4 Cases (2 Illustrative Case Reports Discussed)
Follow-Up	Case 1 Patient followed for approx. 10 years (patient had semi-constrained THR in 1989). Apr. 1993 cup revised with semi-constrained followed by recurrent dislocation Nov. 1993 revised with semi-constrained cup followed by recurrent dislocation Mar. 1994 revised with semi-constrained cup followed by dislocation 2 yrs. postop Feb. 1996 revised with constrained cup and asymptomatic at latest follow-up Case 2 Patient followed for approx. 3 years (patient had comminuted fracture of right acetabulum in 1993) Mar. 1995 semi-constrained right THR followed by recurrent dislocation Oct. 1996 revised with semi-constrained prosthesis followed by recurrent dislocation Dec. 1996 revised cup with constrained S-ROM followed by dislocation and open reduction
Demographic Data	
Age	Case 1 37 years Case 2 35 years
Average Weight	
Sex	2 Females
Indications	Case 1 Revision of previous THR with subsequent recurrent dislocation Case 2 Revision of previous THR with subsequent recurrent dislocation
Primary Diagnosis	Case 1 Degenerative Osteoarthrosis Case 2 Post-Traumatic Osteoarthrosis

Discussion

The author reported on 4 failures by describing 2 illustrative case histories. The author states that 9 additional patients were treated successfully.

Complications	
	2 failures due to fracture of the constraining ring (only 1 resulted in dislocation or instability) 2 revisions resulted from dislocation of the femoral head from the constrained socket

LITERATURE REVIEW TABLE

	Lombardí, A.V., et aI (16) Orthopedics
	J & J S-ROM 1991 55 Patients (57 Hips)
Follow-Up	Ave. 27.7 Months Range 24-3 5 Months
Demographic Data	
Average Age	**69.1** Years Range 39-91 Years
Sex	25 Males 30 Females
Indications	55 patients with multiply revised THR , unstable hips, and neuromuscular and/or neurological conditions associated with THR were treated with the S-ROM constrained hip Indications for 5 1 revision cases were: 3 1 Dislocations 7 Femoral Fractures 6 Aseptic Loosening 4 Resection Arthroplasty w/Flail Hip 3 Conversion Arthrodesis Indications for 6 primary cases were 4 Post Trauma Hip Arthrodesis 2 Osteoarthritis Complicated by Neuromuscular Disease
Primary Diagnosis	Six Primary Cases 1 Post Trauma Hip Arthrodesis 3 Post Trauma Hip Fractures with Intraoperative Instability 2 Osteoarthritis Complicated by Poliomyelitis & Myositis Ossificans Fifty-One Revision Cases 46 Osteoarthristis 2 Rheumatoid Arthritis 2 Avascular Necrosis 1 Congenital Hip Dysplasia
Discussion	

Among the 31 patients who presented with dislocation, the average length of time from previous arthroplasty to dislocation was 3.2 months (range 4 days – 24

months).
Thirteen of these patients had multiple dislocations (average 2.7). Five of these patients were treated with closed reduction, but dislocation occurred again in an average of 2 months.

Safety Data and Effectiveness

Five of 55 patients redislocated a total of 8 times in an average time of 2.5 months from operative procedure to dislocation. Fifty patients have not experienced dislocation after the constrained hip procedure at an average of 30.2 months. The authors historical dislocation rate in 176 revision THR arthroplasties was 19%, but has been lowered to 4.5% ($p<.001$) by use of the constrained hip.

Harris Hip Scores	Preop	Postop(Ave. 30.2 months)
Total	**36.3**	**67.3**
Pain	**19.6**	**37.2**
Function	**13.9**	**23.5**
Deformity	**0.1**	**3.2**
Range of Motion	2.7	3.4

Complications

The five patients who dislocated are reported as case histories.

Case 1 72 year old female with 2 previous revision surgeries dislocated 1 month after insertion of the S-ROM constrained cup. After an open reduction with neck length increase and a cup angle adjustment, patient was fitted with a hip cast brace for 6 mos. and at 24 mos. is ambulatory without redislocation.

Case 2 59 year old man dislocated 2 mos. after insertion of the S-ROM constrained cup resulting from the constraining ring disengaging at 2 weeks postop. Ring and liner were replaced during open reduction. Patient was fitted with hip cast brace for 6 weeks, and at 24 mos. is ambulatory without redislocation.

Case 3 72 year old man with Parkinson's disease experienced recurrent dislocation at 1 and 2 mos. after insertion of the S-ROM constrained cup. Parkinsonism caused chronic positional dislocations, necessitating open reduction and constraining insert change with both dislocations. After the second dislocation, patient was fitted with hip cast brace for 6 weeks and at 22 mos. is ambulatory without redislocation.

Case 4 70 year old woman experienced 2 dislocations at 1 month and 9 months following insertion of the S-ROM constrained cup. The first open reduction showed the insert had rotated, and the insert was changed and

new acetabular angles established. The second open reduction showed extensive wear and dislocation. Again, the insert was changed and patient was fitted with hip cast brace for 6 weeks. Patient is ambulatory at 14 mos. without redislocation.

Case 5 66 year old man experienced 2 posterior dislocations at 2 and 3 mos. postop. After first dislocation, patient underwent adductor tenotomy but dislocation recurred. Because he had an above the knee amputation, a hip cast brace could not be used. Presently, the patient is girdlestoned secondary to hematogenous infectious spread from decubitous ulcer.

Discussion

Constraint has been an adjunct in the management of patients with the difficult problem of chronic dislocations or unstable and/or multiply revised hips. It provides most patients with a viable alternative to repeated dislocations, instability, and loss of mobility.